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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/858,016	05/15/2001	Jane C. Hirsh	21720	4877

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EXAMINER	
GOLLAMUDI, SHARMILA S	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 03/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/858,016	HIRSH ET AL.	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *10/28/04*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

In view of the Appeal Brief filed on 10/28/04 PROSECUTION IS HEREBY REOPENED. As set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Provisional rejection of claims 33, 35, 38-39, 41, 43, 44, 46, and 48 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2, 5-6, 8, 10, and 16 of copending Application No. 10/015930. Although the

conflicting claims are not identical, they are not patentably distinct from each other because both applications contain similar subject matter is maintained.

Instant application claims a composition and a process of preparation with an intraoral portion for sublingual or buccal administration, specific drugs, drug amount, and a second oral portion to be released in the GI tract. Claim 35 recites the composition in a tablet or capsule form. Claims 38-39 claims a film coating. Claim 41 claims an effervescent agent in the outer coating. Claim 43 recites a sustained release formulation. Claims 44 and 46 claim a release rate of 0.5-24 hours. Claim 48 claims the outer layer dissolves within 10 minutes.

Co-pending application claims a composition and a process of preparation with an intraoral portion for sublingual or buccal administration and a second oral portion to be released in the GI tract. Claim 2 recites the composition in a tablet or compressed tablet form. Claim 6 claims a film coating. Claim 5 claims an effervescent agent in the outer coating. Claim 8 and 10 recite a sustained release formulation and a release rate of 0.5-24 hours. Claim 16 claims the outer layer dissolves within 10 minutes.

The two applications are related as genus-species. Co-pending recites a broader composition (genus) and the instant application recites a species of drugs. Thus, the instant application's broad claim is anticipated by the co-pending application broad claim.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant will file a Terminal Disclaimer upon allowance.

The examiner will withdraw rejections after filing of the Terminal Disclaimer.

Response to Arguments

Applicant's arguments with respect to claims 33-57 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 55-57 are under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 57 recites "wherein the active ingredient has a molecular weight of less than 350 Daltons". However, claim 57 depends on the parent claim which recites specific active ingredients in a Markush group. Therefore, the claim is not further limiting the parent claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 33-39, 42-50, 52-53, and 55-57are rejected under 35 U.S.C. 103(a) as being unpatentable over GB 800,973 in view of Powell et al (6,140,319) in further view of DE 3338978.

GB teaches a multi-layered tablet comprising 1) the outer coating contains a medicament that readily dissolves in the mouth 2) a signal layer containing a distinctive flavor and 3) an enteric layer around an oral medicament core to be swallowed. See figures. The outer coat is taught to readily dissolve in the mouth. See column 2, lines 59-65. GB discloses that the enteric layer may be manipulated with a certain thickness to release the medicament in a given area or time, which is known in the art. See page 2.

Example 1 teaches the immediate drug on the outside as N-isopropylarterenol and the delayed core is theophyllin. Example 2 teaches the immediate layer-containing nitroglycerin to promptly treat angina followed by the delayed action of pentaerithrytol in the inner core. The inner core is coated with three coats of shellac and then an alarm layer if coated over this. Thereafter, the tablet is coated with a therapeutic dose of nitroglycerin (10%). Optionally the alarm (flavor) may be contained in the outer medicament coating.

GB does not teach instant drugs as defined in independent claim 33.

Powell teaches vasopeptidase inhibitors to treat angina pectoris. Powell teaches the vasopeptidase inhibitor in combination with other active agents known to treat angina. These agents include nitroglycerin, instant verapamil hydrochloride, instant amlodipine, etc. see column 4, lines 5-15.

DE teaches the use of verapamil in the amount of 5-25mg in a sublingual or buccal tablet. See abstract.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to look to the teachings of Powell and utilize the instant verapamil in GB's nitroglycerin example. One would have been motivated to do so since Powell teaches that the prior art's nitroglycerin and instantly claimed drug verapamil are both utilized to treat angina. Thus, a skilled artisan would have been motivated to substitute nitroglycerin with verapamil with the expectation of similar results since GB teaches the use of nitroglycerin to promptly treat angina and the prior art teaches that both drugs treat angina.

Further, one would have been motivated to look to DE and utilize the instant amount of verapamil since the prior art teaches an amount of 5-25 mg is utilized in a sublingual/buccal tablet.

Note that it is the examiner's position that the prior art's readily dissolvable outer layer will implicitly have the dissolving time of claim 48.

Note that shellac is an enteric coating that provides a sustained release which would fall in to instant range. See art of interest US 6,228,396 wherein the references states that a coating such as shellac provides for a breakup in about 34 hours. See column 3, lines 9-25.

Claims 41, 51, and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB 800,973 in view of Powell et al (6,140,319) in further view of DE 3338978 in further view of Panther et al (6,200,604).

The teachings of GB, Powell, and DE have been set forth above in detail.

GB does not teach the use of an effervescent agent in the outer layer.

Panther teaches a sublingual buccal effervescent which contains an orally administrable drug in combination with an effervescent to promote the absorption of the medicament in the oral cavity. See abstract. Panther teaches the use of the effervescent as a penetration enhancer to influence the permeability of the medicament across the oral mucosa. See column 2, lines 5-11. Panther also teaches the prior art use of effervescent agents in buccal administered dosage forms to mask the taste of the medicament. See column 1, lines 30-40. Lastly, Panther teaches the use of a variety of medicaments including antihypertensive, including the ones disclosed in US patent 5,234,957. US '957 discloses verapamil and nitroglycerin. See column 19, lines 61 and column 20, line 3.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of GB and Panther and utilize an effervescent agent in the rapid onset layer of GB. One would have been motivated to do so since Panther teaches the use of effervescent agents as penetration enhancers in sublingual tablets, which facilitates the permeation of the drug across the oral mucosa. Therefore, a skilled artisan would have been motivated to add an effervescent agent to increase the penetration of the drug through the oral mucosa.

Claims 41-42, 51, and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neuser et al (PGPUB 2001/0002999) in view of Panther et al (6,200,604).

Neuser teaches an analgesic combination wherein the core of the tablet contains a systemically acting analgesic and the outer coating contains a locally acting analgesic. The locally acting analgesic has a rapid onset and the systemic portion has a sustained action for a duration of at least 3 hours. See claim 1 and paragraph 0015. The local analgesic is a drug that has an onset action of one minute and particularly 30 seconds and is utilized in an amount of 2-30mg. See paragraph 0007. The local analgesic is selected from lidocaine (234.34 molecular weight), prilocaine (256.77), procaine (272.77), etc., with a preference for benzocaine (165.19). See paragraph 0009 and 0014.

Neuser does not teach the use of an effervescent layer in the rapid onset layer, i.e. the local analgesic.

Panther teaches a sublingual buccal effervescent which contains an orally administrable drug in combination with an effervescent to promote the absorption of the medicament in the oral cavity. See abstract. Panther teaches the use of the effervescent as a penetration enhancer to influence the permeability of the medicament across the oral mucosa. See column 2, lines 5-11. Panther also teaches the prior art use of effervescent agents in buccal administered dosage forms to mask the taste of the medicament. See column 1, lines 30-40. Lastly, Panther teaches the use of a variety of medicaments including the ones disclosed in US patent 5,234,957. US '957 discloses local anesthetics such as lidocaine, prilocaine, benzocaine. See column 5, lines 55-68.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Neuser et al and Panther and utilize an effervescent agent

in the rapid onset layer of Neuser. One would have been motivated to do so since Panther teaches the use of effervescent agents as penetration enhancers in sublingual tablets, which facilitates the permeation of the drug across the oral mucosa. Therefore, a skilled artisan would have been motivated to add an efferevescent agent to increase the penetration of the drug through the oral mucosa.

Claims 33-43 and 49-57 under 35 U.S.C. 103(a) as being unpatentable over Barclay et al (5,053,032) in view of Panther et al (6,200,604).

Barclay et al disclose an osmotic device for delivering a beneficial agent. Barclay's tablet houses two regions, one for delivering a predetermined dosage via buccal administration of a drug and a second region for delivering the remainder of the dose to the GI tract (Note abstract, col. 8, lines 28-51). Further, the tablet contains a signaling in the form of a flavoring agent or coloring agent that alerts the patient that the buccal administration dosage has been delivered and the remainder may be swallowed (col. 3, lines 57-68, col. 5, lines 25-55). In a preferred embodiment the first active agent as a first flavor and the hydrophilic polymer layer containing the second portion contains a second flavoring agent. See column 5, lines 25-55. The reference discloses several drugs including instant drug prochlorperazine, nitroglycerine (227.09), ibuprofen (206.28), naproxen (230.26), levodopa (197.19), etc. that are suitable for the delivery device on column 10, line 50 to column 11, line 35. The drug is used in an amount of 0.05ng to 500 mg. See column 12, lines 23. Barclay discloses the process of making the device and compression of the layers (example 1). Osmagents such as sodium carbonate are taught in the osmotic device. See column 12 lines 27-45 and example 3. The device delivers the active agent over an extended period of time, i.e. 0.5-12 hours. See column 15, lines 15-20.

Example 3 discloses an oral osmotic device wherein the inner core contains 20.5 ibuprofen (206.28), 66.5% polyox, 5% HPMC, 7.5% sodium carbonate, and 0.5% magnesium stearate. This core is coated with a layer containing 20% ibuprofen and 80% HPMC. The overcoat layer is completely removed within about 15 minutes to 30 minutes. Further, the device contains a color-coding signaling system.

Although, Barclay teaches the instant drug prochlorperazine of independent claim 33, Barclay does not exemplify it and its dosage amount. Secondly, Barclay does not teach the use of an effervescent agent in the buccal region as claimed in independent clam 41.

Panther teaches a sublingual buccal effervescent which contains an orally administerable drug in combination with an effervescent to promote the absorption of the medicament in the oral cavity. See abstract. Panther teaches the use of the effervescent as a penetration enhancer to influence the permeability of the medicament across the oral mucosa. See column 2, lines 5-11. Panther also teaches the prior art use of effervescent agents in buccal administered dosage forms to mask the taste of the medicament. See column 1, lines 30-40. Lastly, Panther teaches the use of a variety of medicaments in the sublingual formula. Panther exemplifies the use of prochlorperazine in the amount of 5 mg. See example 2. Lastly, Panther teaches the use of a variety of medicaments including the ones disclosed in US patent 5,234,957. US '957 discloses of drugs such as ibuprofen.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Barclay et al and Panther and utilize an effervescent agent in the buccal region of Barclay's device. One would have been motivated to do so since Panther teaches the use of effervescent agents as penetration enhancers in sublingual/buccal tablets,

which facilitates the permeation of the drug across the oral mucosa. Therefore, a skilled artisan would have been motivated to add an effervescent agent to increase the penetration of the drug through the oral mucosa. Moreover, Panther teaches the instant amount of the instant prochlorperazine utilized in the formulation. Therefore, the instant invention is prima facie obvious.

With regard to claim 47, it is the examiner's position that the recitation "wherein the second oral portion is chewable and comprises at least one pharmaceutically acceptable excipient suitable for chewable medication" is intended use. Further, if the prior art structure is capable of performing the said intended use, then it meets the intended use. In the instant case, Barclay's GI portion is capable of being chewed and the excipients used in the core are also capable of being chewed, thus it meets the claim limitation.

Pertinent Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US patent 5,702,723 to Griffin, wherein Griffin teaches a multi-stage pill that has an internally acting medicine in the core and a locally acting medicament in the outer layer.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila S. Gollamudi
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